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Signed P. Mahoney

Dated 9 November 2004

GB 0325715.1

By virtue of a direction given under Section 30 of the Patents Act 1977, the application is proceeding in the name of:

CRANE PROCESS FLOW TECHNOLOGIES LTD,
Grange Road,
CWMBRAN,
Gwent,
NP44 3XX,
United Kingdom

Incorporated in the United Kingdom,

[ADP No. 08592149001]

and

ALFA LAVAL BIOKINETICS INC.,
1635 Market Street,
Suite 1500,
Philadelphia,
PA 19103,
United States of America

Incorporated in USA - Delaware,

[ADP No. 08864332001]

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1. Your reference — NG/22015

E849397-15 000180
P01/7700 0.00-0325715.1

2. Patent application number
(The Patent Office will fill in this part) — 04 NOV 2003 — 0325715.1

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

CRANE PROCESS FLOW TECHNOLOGIES LTD

Grange Road
Cwmbran
Gwent NP44 3XX

Patents ADP number *(if you know it)* 08592149001

If the applicant is a corporate body, give the country/state of its incorporation — GB

SECTION 15(4) (1977 ACT) APPLICATION FILED 28/4/04

4. Title of the invention — SINGLE USE DIAPHRAGM VALVE BODY

5. Name of your agent *(if you have one)*

A A THORNTON & CO

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

235 HIGH HOLBORN
LONDON WC1V 7LE

75001

Patents ADP number *(if you know it)*

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
See note (d))

YES

Patents Form 1/77

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Continuation sheets of this form	
Description	9
Claim(s)	- DL
Abstract	-
Drawing(s)	9 + 9

10. If you are also filing any of the following, state how many against each item.

Priority documents	
Translations of priority documents	
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	-
Request for preliminary examination and search *(Patents Form 9/77)*	-
Request for substantive examination *(Patents Form 10/77)*	
Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

Signature [signature] Date 03/11/03

12. Name and daytime telephone number of person to contact in the United Kingdom: NIGEL GOODENOUGH - 01604 638242

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SINGLE USE DIAPHRAGM VALVE BODY

This invention relates to a diaphragm valve, and more particularly to a diaphragm valve having a body which is disposable.

A diaphragm valve comprises a valve body having a diaphragm opening to which a diaphragm is sealed. The valve body and diaphragm together define a flow passage which extends between an inlet port and an outlet port, both defined by the valve body. An operating mechanism is secured to the valve body for moving the diaphragm into sealing engagement with a seat provided on the valve body in order to close the flow passage to fluid flow.

Diaphragm valves have gained wide acceptance in many industries. One reason for the success of diaphragm valves in many industries is the fact that the line content is totally contained within the flow passage defined by the valve body and the diaphragm, and accordingly does not come into contact with any components of the valve other than the diaphragm and this body. This renders diaphragm valves particularly suitable for handling hazardous materials, or for use in applications where high levels of purity are required. For this reason, diaphragm valves have wide acceptance in the biotechnology industry.

It is of critical importance in the biotechnology industry in particular that process equipment can be thoroughly cleaned. Although existing diaphragm valves do admit to thorough cleaning by use of cleaning chemicals and/or steam, ensuring absolute cleanliness with existing diaphragm valves is difficult. It may, for example, be necessary, after initial cleaning, to dis-assemble a diaphragm valves in order to carry out a validity check on the sterility of the system. Such cleaning processes are both time consuming and subject to operator error. Even if, in a particular application, dis-assembly of the valve after initial cleaning is not considered to be necessary, the initial cleaning phase using cleaning chemicals and/or steam cleaning must be carried out thoroughly to achieve a high level of cleanliness. Accordingly, even if valve dis-

assembly is not necessary high quality cleaning procedures associated with process plant incorporating diaphragm valves are time consuming (and thus costly) and subject to operator error.

Accordingly, the present invention proposes a diaphragm valve in which the body and the diaphragm are "disposable". With such a valve, the valve in its entirety may be removed from a process line and the valve body and diaphragm replaced with a new valve body and diaphragms. Alternatively, only the valve body and diaphragm need be removed and replaced, whilst the remaining components of the valve are left in situ. Such replacement may take place instead of thorough cleaning of the valve or at specified intervals in order to prevent the build-up of contaminants within the valve.

Because it is a characteristic of diaphragm valves that the operating mechanism (compressor and actuator) does not come into contact with the line fluid it should not be necessary to dispose of these components when the body itself is disposed of.

Accordingly, it is the primary object of the present invention to provide a diaphragm valve in which the diaphragm and valve body may be disposed of and in which other components of the valve may be re-used in combination with a replacement valve body and diaphragm.

At first sight, the object of the present invention can be achieved simply by replacing a conventional valve body (which is typically of polished forged or cast stainless steel) with a moulded plastics valve body of the same profile. However, this is not possible because the mechanical characteristics of conventional metal valve bodies cannot be reproduced using plastics materials. In particular, the conventional arrangement whereby the closure diaphragm is sealed to the body by clamping the periphery of the diaphragm between respective flanges provided on the body and on the actuating mechanism is not possible if the body is formed of plastics material, in particular flexible plastics material.

In accordance with the first aspect of the present invention a diaphragm valve comprising: a valve body having a diaphragm opening surrounded by a sealing surface; a diaphragm which is sealed to the sealing surface to define with the valve

body a flow passage which extends between an inlet port and an outlet port, both defined by the valve body; and operating mechanism secured to the valve body for moving the diaphragm into sealing engagement with a seat provided on the valve body in order to close the flow passage to fluid flow, is characterised in that the sealing surface of the valve body is surrounded by a wall which is upstanding from the outer periphery of the sealing surface to define a recess in which the periphery of the diaphragm is, in use, located, and a diaphragm retaining member is secured to the valve body, the diaphragm retaining member including a projection which extends into the recess to engage the diaphragm and compress it between the projection and the sealing surface of the valve body.

The diaphragm locating arrangement in accordance with the present invention substantially obviates the problems of diaphragm mounting which would exist if a conventionally shaped valve body was formed of plastics material.

The diaphragm body and diaphragm may be pre-assembled and supplied as a single assembly for insertion by a user in place of a previously used assembly. The diaphragm retaining member may similarly be supplied as part of the pre-assembled combination. Alternatively, the diaphragm retaining member may be part of an operating mechanism which is releasably secured to the body/diaphragm assembly at the time of installation of the new body/diaphragm assembly.

The invention will be better understood from the following description of embodiments thereof, given by way of example only, reference being had to the accompanying drawings wherein:

Figure 1 shows schematically an embodiment of the present invention in the form of a diaphragm valve having a reusable operating mechanism and a disposable body and diaphragm assembly;

Figure 2 illustrates an alternative embodiment of the invention in which a disposable assembly comprising a valve body, diaphragm and diaphragm retaining member is attached to a reusable operating mechanism;

Figure 3 illustrates the valve body of the embodiment of Figure 2;

Figure 4 illustrates the valve body and diaphragm retaining member of the embodiment of Figure 2;

Figures 5-7 illustrate alternative arrangements for securing a diaphragm retaining member to a valve body;

Figure 8 illustrates an arrangement for securing an operating mechanism directly to a valve body; and

Figure 9 illustrates a diaphragm for use in the preceding embodiments of the invention.

Referring firstly to Figure 1 there is shown a diaphragm valve 1 comprising a body 2 and an operating mechanism 3. As will be understood by those skilled in the art a diaphragm (not visible in Figure 1) closes a diaphragm opening provided in the valve body 2 and is connected to a compressor which forms part of the operating mechanism 3. The compressor is acted upon by an actuator which also forms part of the operating mechanism 3 in order to move the diaphragm between a closed position in which it sealingly engages a seat provided in the valve body to close a flow passage 4 to fluid flow and an open position in which the flow passage is open to permit fluid to flow between an inlet port 5 located at one end of the valve body and an outlet port (not visible in Figure 1) located at the opposite end of the valve body.

In the diaphragm valve of Figure 1, the valve body 2 and diaphragm are disposable whilst the operating mechanism 3 is re-usable. To this end, quick release clamps 6 and 7 are provided for releasably securing the valve body to adjacent components in a pipework system and a releasable clamp 8 is provided for releasably securing the operating mechanism 3 to the valve body 2. The exact frequency with which the valve body 2 will be replaced in use will depend on the nature of the process in which the valve is used. Typically, in high purity applications in the biotechnology industry it is intended that the valve body 2 will be replaced each and every time that the system is cleaned. In other applications, however, replacement of the valve body may occur at specified time intervals, depending on the nature of the process in which the valve is utilised.

Referring now to Figure 2 an alternative design of diaphragm valve 10 is illustrated. This design incorporates a disposable valve body 11 and a disposable diaphragm (not visible from Figure 2). In this case the diaphragm is secured and sealed to the valve body by a diaphragm retaining member 12 which forms part of a disposable assembly 14 comprising the valve body 11, the diaphragm and the diaphragm retaining member 12. An operating mechanism 13 is releasably secured to the diaphragm retaining member 12 so that when the disposable assembly 14 is replaced, the operating mechanism 13 can be secured to a new assembly.

Referring now to Figure 3, the valve body 11 of the valve of Figure 2 is illustrated in greater detail. The valve body will be seen to define an inlet port 15 and an outlet port 16. The valve body illustrated is, in fact, symmetrical so that either port may function as an inlet port whilst the other port functions as an outlet port. A flow passage 17 is in part defined within the valve body to provide communication between the ports 15 and 16. A diaphragm opening 18 is defined by the valve body. In use, the diaphragm opening 18 is closed by a flexible closure diaphragm the diaphragm accordingly partly defines the flow passage.

The diaphragm opening 18 is surrounded by a sealing surface 19 against which the periphery of the diaphragm is, in use, sealed. The diaphragm sealing surface 19 is generally planar but may include surface profile features (for example one or more ridges or grooves) in order to assist the formation of a fluid tight seal between the diaphragm and the sealing surface. As will be appreciated by those skilled in the art, when the diaphragm is in position and sealed to the sealing surface 19 the flow passage 17 is entirely defined by the valve body and the diaphragm and line content will not come into contact with any other components of the valve.

The valve body 11 defines a weir 20 the upper surface of which defines a seat 21. The operating mechanism which is used with the valve body is capable of forcing the diaphragm into sealing engagement with the seat 21 in order to close the flow passage 17 to fluid flow. Preferably, the operating mechanism is also capable of moving the diaphragm away from the seat 21 so that the valve may be open to fluid

flow even if the line content is at sub-ambient pressure.

The sealing surface 19 is surrounded by a wall 22. In the illustrated embodiment the wall 22 is cylindrical, the surface of the wall 22 at any point being perpendicular to the adjacent portion of the sealing surface 19. The sealing surface 19 and wall 20 accordingly define a recess 25 in which the periphery of the diaphragm is, in use, located.

Referring now to Figure 4, a diaphragm retaining member 23 is, in use, secured to the valve 11 to retain the diaphragm and hold the diaphragm in sealing engagement with the sealing surface 19. The diaphragm retaining member 23 includes a projection 24 which is a snug-fit within the recess 25 defined by the valve body. The diaphragm retaining member 23 also includes an outwardly projecting flange 26 which engages a corresponding flange 27 provided on the valve body. The components are sized such that when the flanges 26 and 27 are in contact with each other the spacing between the free end 28 of the projection 24 and the sealing surface 19 is correct relative to the thickness of the diaphragm to ensure the required sealing contact and mechanical support of the diaphragm relative to the valve body. Preferably, the projection 24 includes a chamfered surface 29 so that the projection 24 and body 11 together defined an undercut region at the outer periphery of the diaphragm. Preferably, the diaphragm is moulded with a projection corresponding to the undercut region so that the periphery of the diaphragm is mechanically clamped against radially inward movement.

The seal between the diaphragm and the sealing surface 19 may be produced purely by resilient deformation of the material of the diaphragm against the sealing surface 19. However, it is within the scope of the invention for positive sealing at this point to be effected by use, for example, of an adhesive or sealing compound or by welding of the material of the diaphragm to the valve body.

Similarly, the diaphragm retaining member 23 may be secured to the valve body 11 solely by mechanical clamping or may be secured additionally or exclusively by means of adhesive or welding. The object, in all cases, is to provide a disposable

assembly which may comprise the valve body 11 and the diaphragm only or may comprise the valve body 11, the diaphragm and the diaphragm retaining member 23. In all cases, means will be provided for releasably securing an operating mechanism to the disposable assembly so that, when the assembly is to be disposed of, the operating mechanism may be retained and secured to the replacement assembly.

Referring now to Figures 5 – 7 various releasable arrangements for securing a diaphragm retaining member to a valve body are illustrated.

Referring firstly to Figure 5, the illustrated diaphragm retaining member 30 is secured to a valve body 31 by means of clamps 32 which engage projections 33, 34 on the diaphragm retaining member 30 and valve body 31 respectively. The projections 33, 34 and/or the clamps 32 define tapering surfaces such that as the clamps 32 are pushed onto the projections 33, 34 the diaphragm retaining member 30 and body 31 are brought into the required relative position. The clamps 32 may be releasable or may be locked in their final position by mechanical detents, adhesive, welding, or the like. As illustrated, one clamp 32 is provided on each of two opposite sides of the valve body. However, other arrangements are possible. For example, clamps can be provided on all four faces of the valve body. Further, rather than one large clamp two or more small clamps can be provided on some or all of the sides.

Turning now to Figure 6 the diaphragm retaining member 35 is secured to the body 36 by over-centre toggle clamps 37,38. As with the arrangement of Figure 5, clamps may be provided on two only of the sides of the diaphragm retaining member or on all four sides and one, two or more clamps may be provided on one or more of the sides according to the particular design required.

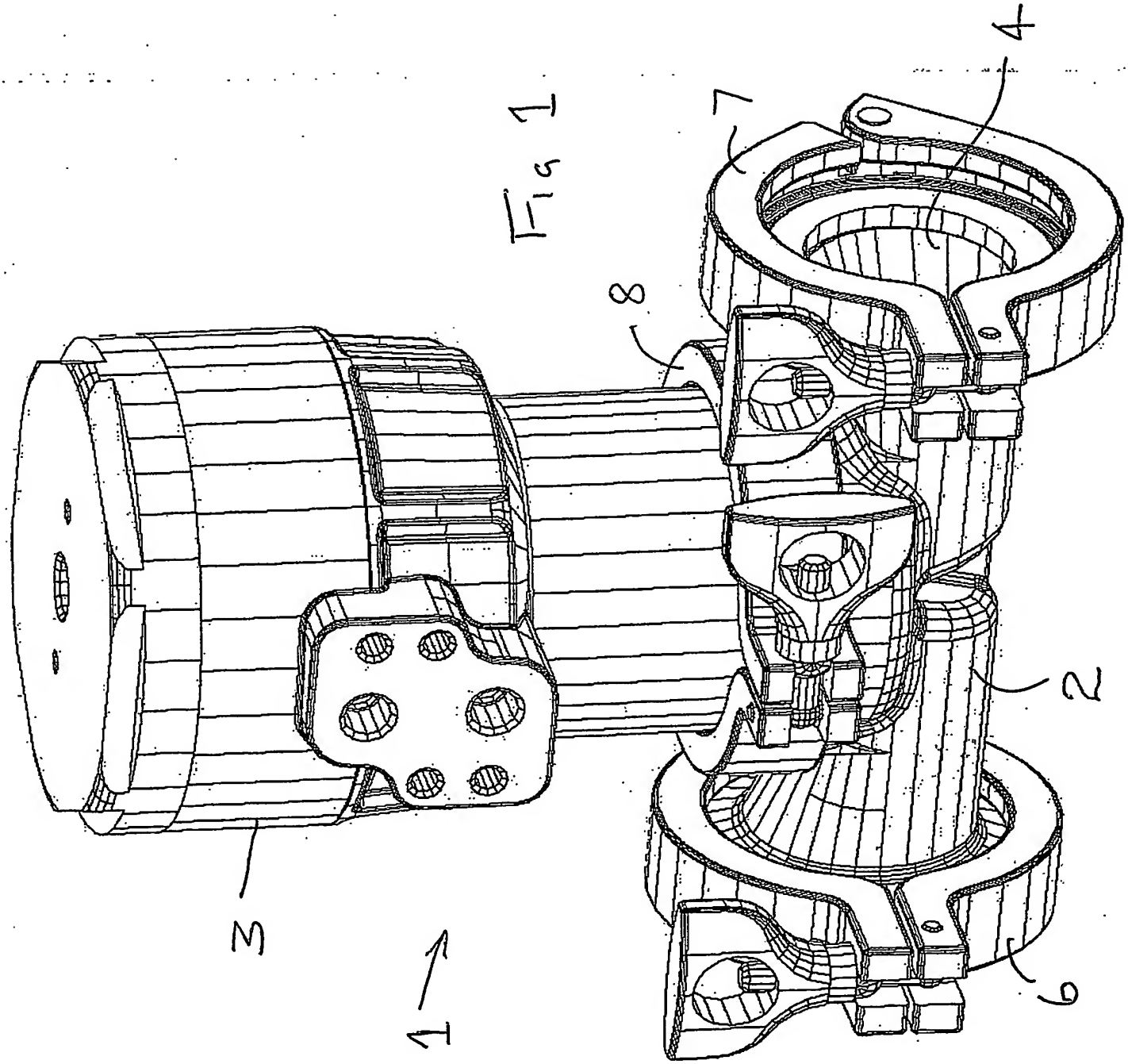
Referring now to Figure 7, the diaphragm retaining member 39 is secured to the valve body 40 by a saddle clamp 41 which includes projections 42 which overlie an upper surface of the diaphragm retaining member 39 and a cam-lever 43 which may be rotated about a pivot pin 44 to engage the under surface of the valve body 40 and thereby draw the diaphragm retaining member 39 into the required position relative to the valve body.

Referring now to Figure 8, an alternative arrangement is illustrated. In this arrangement a valve body 45 similar to that illustrated in Figure 3 is used, but no separate diaphragm retaining member is utilised. Instead, the operating mechanism 48 acts as a diaphragm retaining member and the valve body 45 is formed with bayonet slots 46 which are engaged by bayonet pins 47 provided on the bottom of an operating mechanism 48. In this case, the operating mechanism 48 is released from the valve body/diaphragm assembly by rotating the operating mechanism 48 relative to the valve body to release the bayonet pins 47 of the operating mechanism from the corresponding bayonet slots 46 of the body. After the body has been replaced, the operating mechanism is secured to the replacement body by a reversal of this procedure.

Referring now to Figure 9 a diaphragm 50 suitable for use in the previously described embodiments of the invention is shown. The diaphragm is formed of a flexible and extensible material so that it can be moved by the operating mechanism as required by the valve design. Generally, the diaphragm 50 will be formed of an elastomeric/polymeric material, possibly with the addition of fibre or fabric reinforcement. The diaphragm may be faced with a chemically resistant facing, for example of a fluoro-carbon polymer. The periphery 51 of the diaphragm closely matches the diameter of the recess 25. The peripheral region 52 of the underside of the diaphragm in use forms a seal with the sealing surface 19. The region 52 may be generally planar or may be formed with surface features to enhance sealing. The peripheral region 53 of the upper surface of the diaphragm includes a projection 54 which is complementary to the chamfer 29 provided on the diaphragm retaining member. A stud 55 is moulded into the central region of the diaphragm to provide a mechanical connection between the diaphragm and the compressor of the operating mechanism. The stud 55 may be provided with any appropriate form of mechanical connection to the compressor. Instead of a moulded in stud 55, a specially shaped portion of the material of the diaphragm may, in the alternative, be provided to facilitate mechanical connection between the diaphragm and the compressor.

Whilst the invention has been described in the context of a 2-port valve it is to be understood that the present invention is applicable to other forms of valve, for example valves with three or more ports controlled by one or more diaphragms. The exact arrangements of the valve body, diaphragm and operating mechanism will, of course, be determined by the number of ports present in the valve, but the general concepts of the present invention may be applied to such multi-port valves and the present application is to be construed as encompassing such multi-port valves.

Fig 1



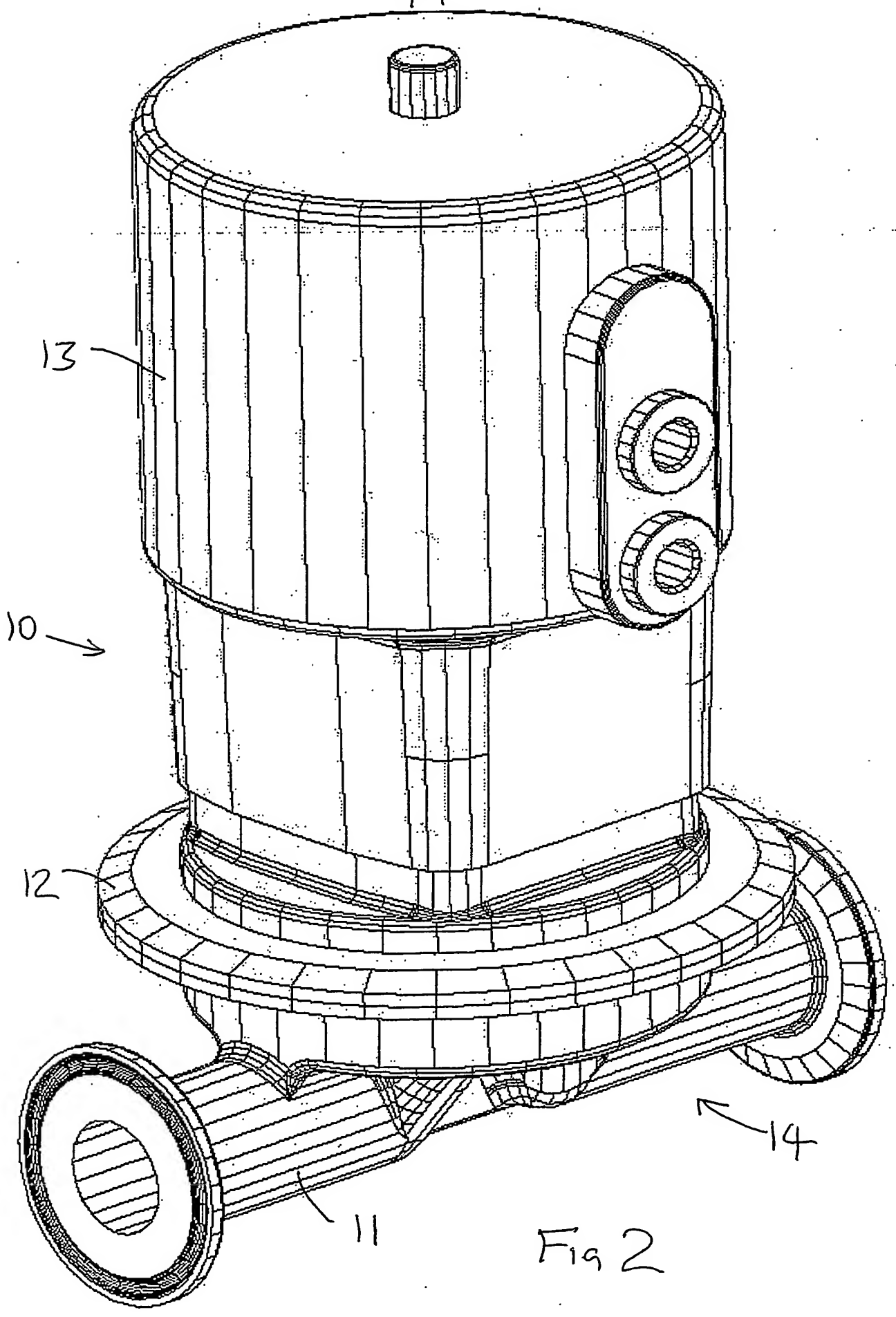


Fig 2

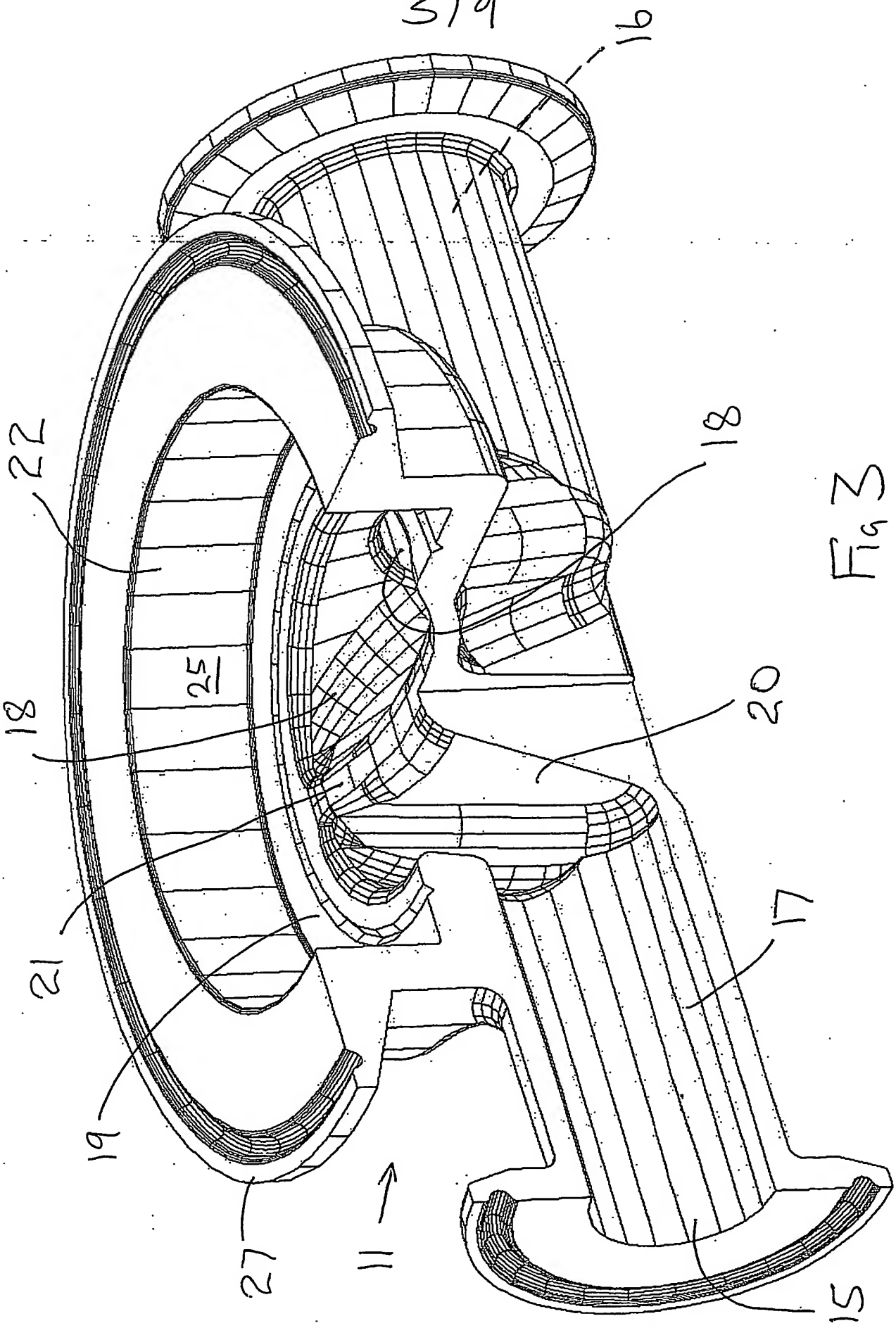


Fig 3

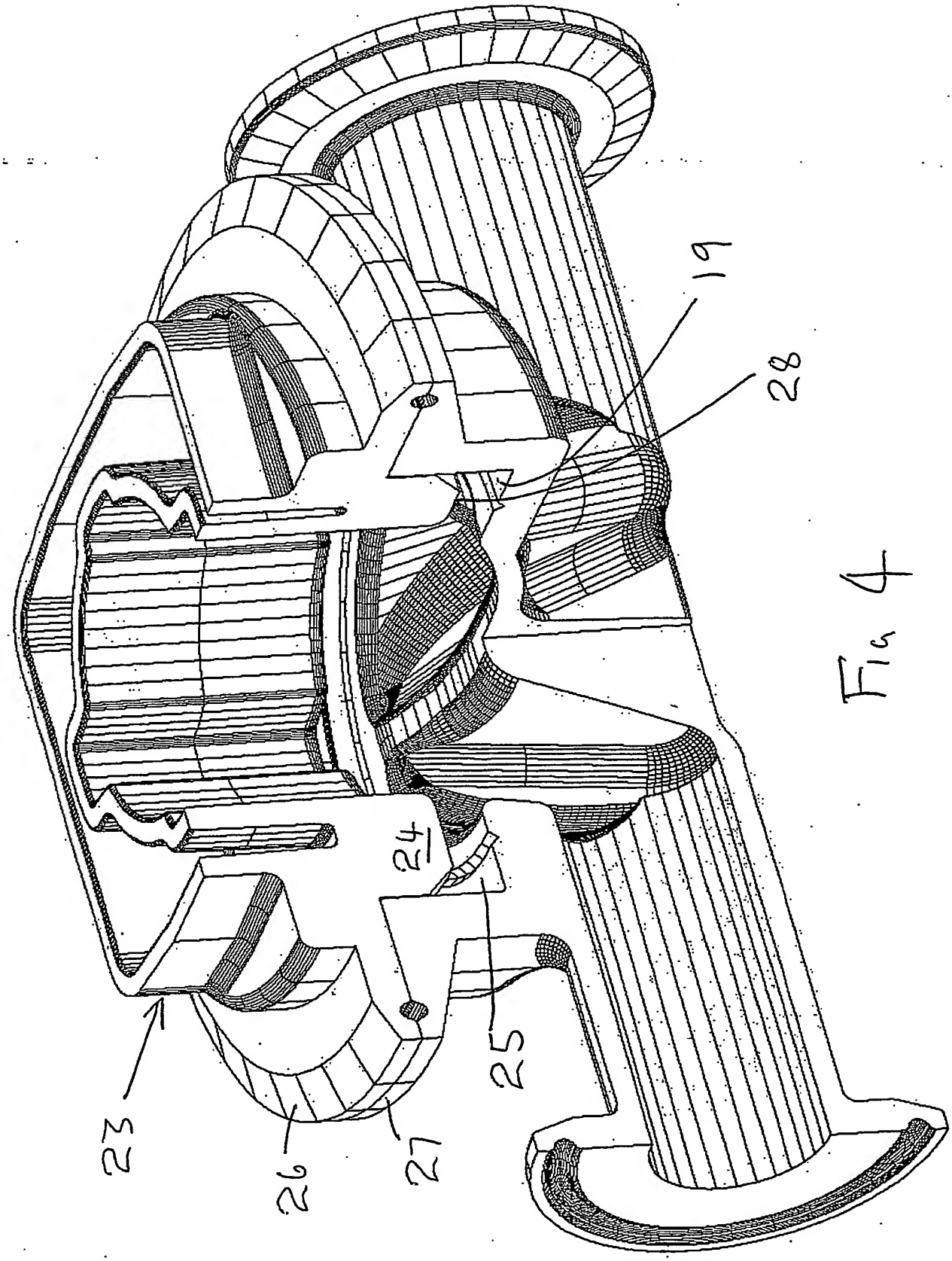


Fig 4

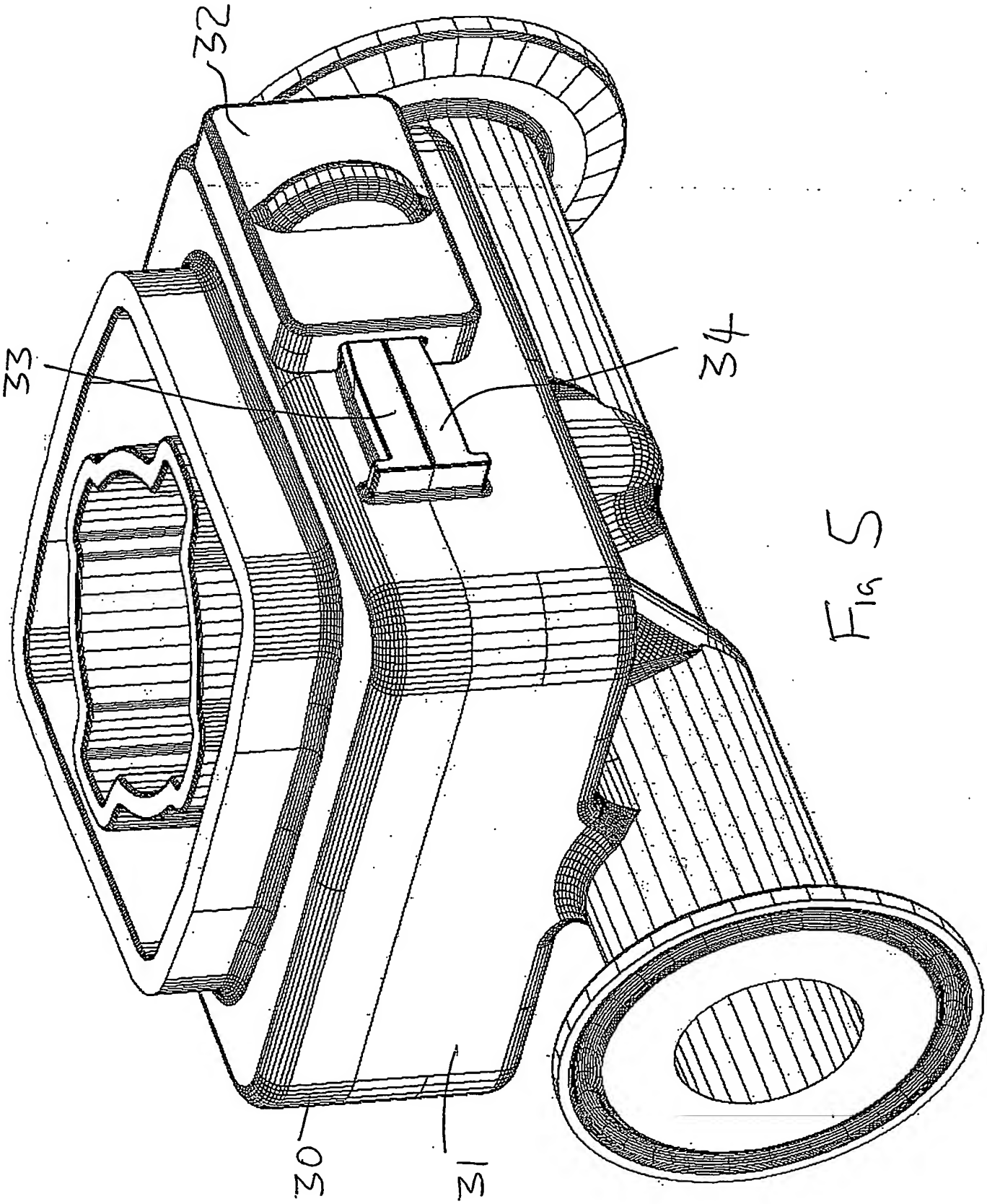


Fig 5

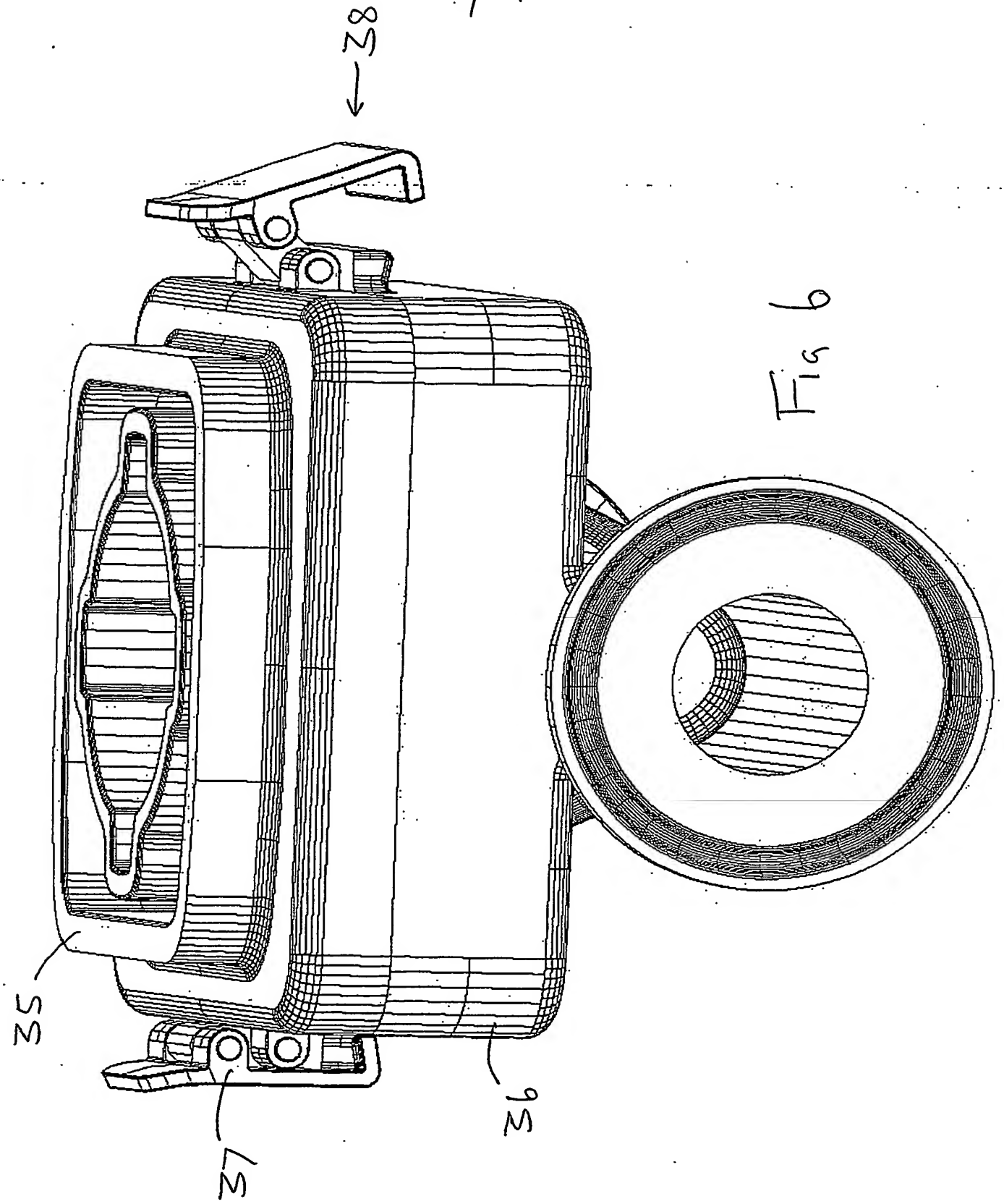


Fig 6

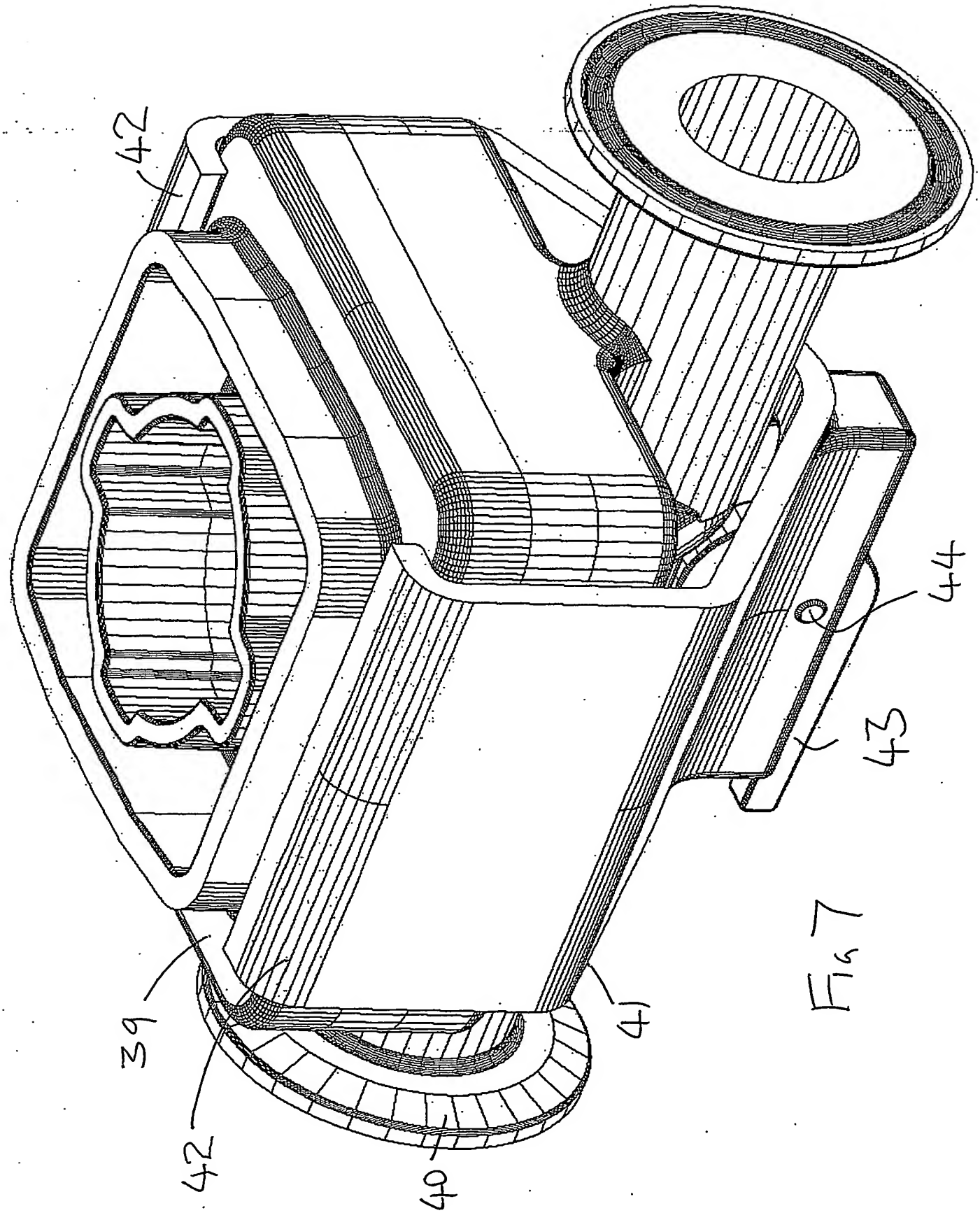


Fig 7

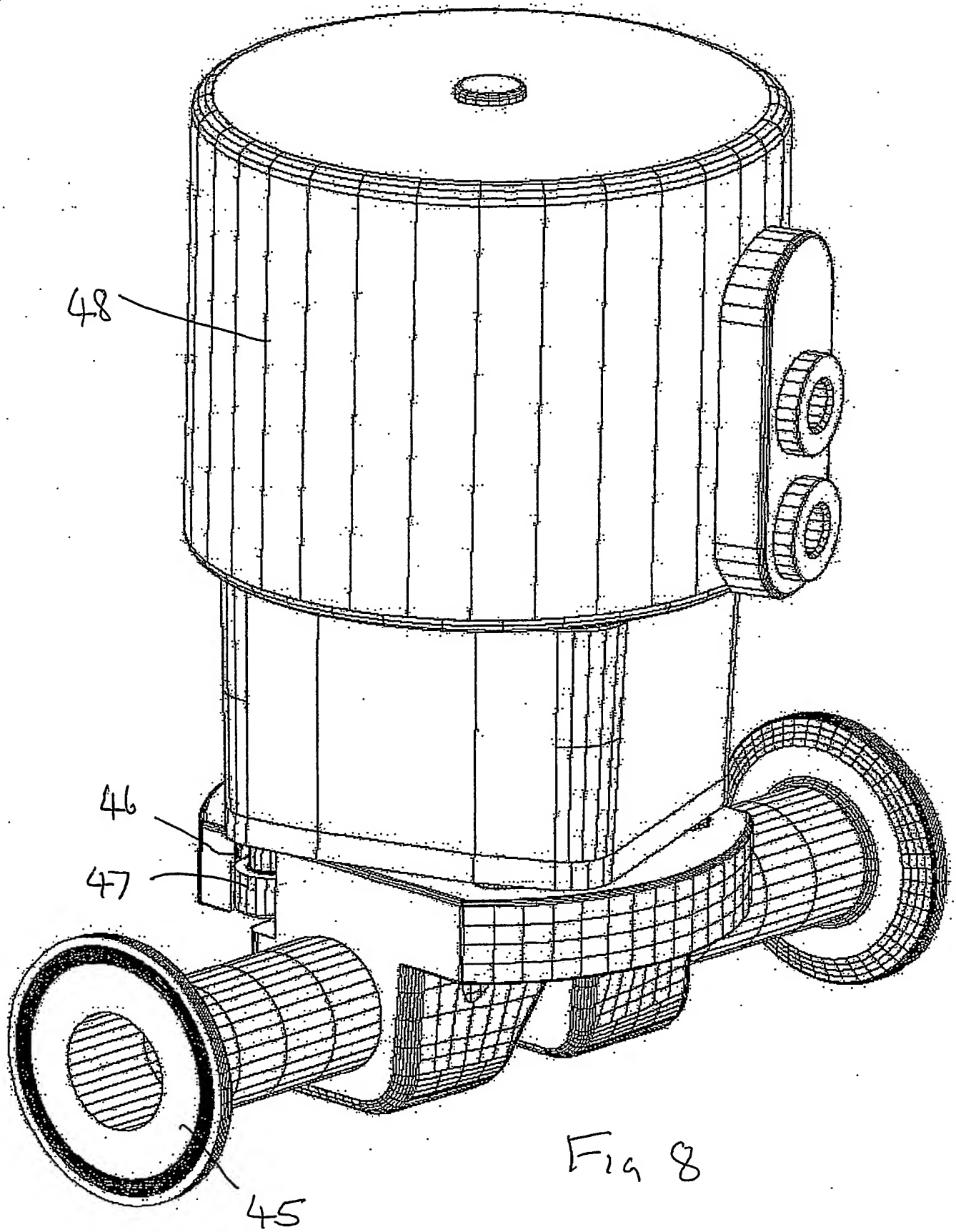


Fig 8

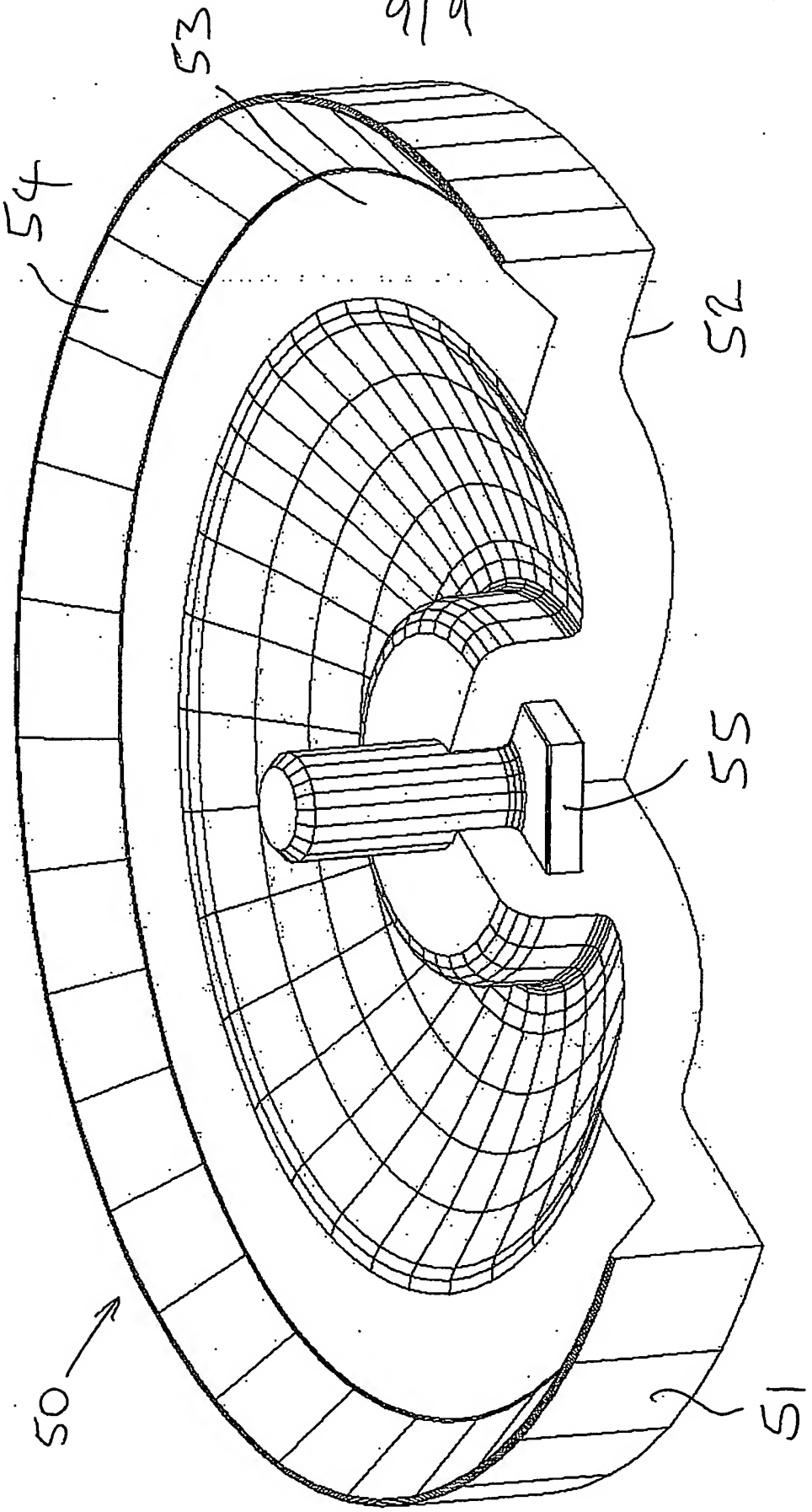


Fig 9